

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of)	
François SCHUTZE et al.)	Group Art Unit: 1614
Application No.: 10/532,114)	Examiner: PHYLLIS G SPIVACK
Filed: April 21, 2005)	Confirmation No.: 9051
For: PHARMACEUTICAL COMPOSITION)	
COMBINING TENATOPRAZOLE)	
AND A HISTAMINE H-2 RECEPTOR)	
ANTAGONIST)	

COMMUNICATION:
REQUEST TO RE-ISSUE OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

A phone call from Examiner Spivack on 22 September 2008 brought to our attention that a Final Office Action was mailed on 19 March 2008 in the above-identified application. An initial check of Applicants' representatives' docket system indicated no outstanding Office Action. Accordingly, Applicants' representatives checked the transaction history of the application through the Patent Application Information Retrieval (PAIR) website.

The PAIR transaction history for this application indicated that a Final Office Action was mailed on 19 March 2008 to Buchanan Ingersoll & Rooney PC, P.O. Box 1404, Alexandria, Virginia , 22313-1404. Also, as provided by PAIR, a request for Change of Address was submitted to the Patent Office on 13 March 2008, changing the official correspondence address from Buchanan Ingersoll & Rooney to Crowell & Moring LLP, Intellectual Property Group, P.O. Box 14300, Washington, DC 20044-4300. The Correspondence Address Change was entered into the record on 17 March 2008, prior to the Final Office Action's mail date. Accordingly, the Final Office Action was not mailed to the correspondence address of record.

The Final Office Action mailed to Buchanan Ingersoll & Rooney, P.O. Box 1404, Alexandria, Virginia , 22313-1404 was not received at Crowell & Moring LLP, the official correspondence address of record.

Because the Final Office Action mailed 19 March 2008 was not received by Applicants' representatives at the official correspondence address, Applicants did not know of and were not able to respond to the outstanding Office Action. However, Applicants have **no** intention of allowing the application to go abandoned. Accordingly, Applicants respectfully request that the Final Office Action be resent to the official correspondence address of record with a new mailing date and the time period for response be reset in accordance with the new mailing date.

In support of this request, Applicants attach hereto the following documents:

- (a) copy of the transaction history page from PAIR showing the Final Rejection mailed on 19 March 2008 and showing the Correspondence Address Change entered on 17 March 2008;
- (b) copy of the Office Action mailed 19 March 2008 accessed from PAIR showing the incorrect addressee;
- (c) copy of Correspondence Address/Fee Address Change; and
- (d) copy of the docket record for the above-identified application generated by Applicants' representatives' docketing software where the non-received Final Office Action would have been entered had it been received. The docket record shows that last activity in this application was the filing of a Response to Office Action on 7 December 2007 with a three-month extension of time. A Final Rejection was not entered into the docketing record.

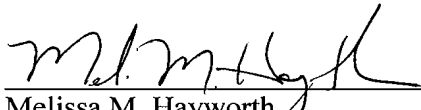
Applicants respectfully request that the Final Office Action be resent to the official correspondence address of record, Crowell and Moring LLP, Intellectual Property Group, P.O. Box 14300, Washington, DC 20044-4300 and that the time period for submission of a response be reset in accordance with the new mailing date. As such, Applicants respectfully submit that the application should **not** be held abandoned.

Applicants respectfully submit that no fees should be due in accordance with this request; however, if any fees are necessary, please charge Deposit Account No. 05-1323 (Docket #104006-B130119).

Please contact the undersigned should you have any questions regarding this communication and request.

Respectfully submitted,

Date: 25 September 2008

By: 
Melissa M. Hayworth
Registration No. 45,774

Crowell & Moring LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
202-624-2500

10/532,114

Pharmaceutical composition combining tenatoprazole and a histamine h2-receptor antagonist

09-22-

2008:12:47:12

Transaction History

Date	Transaction Description
03-17-2008	Correspondence Address Change
03-19-2008	Mail Final Rejection (PTOL - 326)
03-10-2008	Final Rejection
01-06-2008	Date Forwarded to Examiner
12-07-2007	Response after Non-Final Action
12-07-2007	Request for Extension of Time - Granted
06-07-2007	Mail Non-Final Rejection
06-05-2007	Non-Final Rejection
04-12-2007	Information Disclosure Statement considered
04-12-2007	Reference capture on IDS
04-12-2007	Information Disclosure Statement (IDS) Filed
04-21-2005	Information Disclosure Statement considered
04-21-2005	Information Disclosure Statement (IDS) Filed
04-12-2007	Information Disclosure Statement (IDS) Filed
03-27-2007	Date Forwarded to Examiner
03-12-2007	Response after Non-Final Action
03-12-2007	Request for Extension of Time - Granted
09-11-2006	Mail Non-Final Rejection
09-05-2006	Non-Final Rejection
08-04-2006	IFW TSS Processing by Tech Center Complete
08-04-2006	Case Docketed to Examiner in GAU
04-21-2005	Request for Foreign Priority (Priority Papers May Be Included)
04-21-2005	Preliminary Amendment
06-23-2006	371 Completion Date
07-19-2006	Application Dispatched from OIPE
07-19-2006	Notice of DO/EO Acceptance Mailed
06-23-2006	Additional Application Filing Fees
06-23-2006	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applicant
07-14-2006	Mail-Petition Decision - Granted
06-23-2006	Petition Entered
06-19-2006	Mail-Petition Decision - Dismissed
04-03-2006	Petition Entered
02-07-2006	Notice of DO/EO Missing Requirements Mailed
02-06-2006	Cleared by OIPE CSR
02-06-2006	Cleared by OIPE CSR
04-21-2005	Initial Exam Team nn

Close Window



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,114	06/23/2006	Francois Schutze	032013-119	9051

21839 7590 03/19/2008
BUCHANAN, INGERSOLL & ROONEY PC
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

NOTIFICATION DATE	DELIVERY MODE
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03/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/532,114	Applicant(s) SCHUTZE ET AL.	
	Examiner Phyllis G. Spivack	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Amendment filed December 7, 2007 is acknowledged. Claims 1-6 and 9-18 remain under consideration.

In the last Office Action claims 1-6 and 9-18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Brulls, M., U.S. Patent 6,730,685, in view of Facts & Comparisons. It was asserted Brulls teaches pharmaceutical compositions that are combinations of tenatoprazole and H₂-blockers, such as ranitidine. See column 7, lines 22-26. Tenatoprazole is exemplified as a compound of Formula I at the top of column 12. Brulls' teaching is drawn to treatment of diseases relating to gastric hyperacidity, such as gastric and duodenal ulcers and reflux esophagitis, as required by instant claims 17 and 18. See columns 6-7 under Use of the Invention. A dosage range for tenatoprazole is taught to be 1-100 mg once or twice a day (column 7, lines 14-15). Both oral and parenteral administration is disclosed in column 3, lines 1-8. As required by instant claim 5, sodium or potassium salts are disclosed in claims 4 and 5. As required by instant claims 4, 6, 10 and 11, Facts & Comparisons teaches an oral dose of the H₂-blocker ranitidine to be 150 mg and a parenteral dose to be 50 mg.

Applicants argue the combination of tenatoprazole and a histamine H₂-receptor antagonist yields unexpected and superior results compared to the administration of other proton pump inhibitors and other histamine H₂-receptor antagonists, used alone or in combination. Further, Applicants urge Brulls is not specifically directed to tenatoprazole but rather to a general description of all proton pump inhibitors and Facts & Comparisons merely relates to ranitidine, as well as information on dosing, pharmacokinetics and indications of use.

Those proton pump inhibitors contemplated in Brulls' disclosure are clearly set forth in Columns 11 and 12. Tenatoprazole is the first compound at the top of column 12. Formulations

comprising a combination of a proton pump inhibitor and a H₂-blocker are clearly encompassed in Brulls' disclosure. See column 7, lines 22-26. No unexpected results are shown in Table 2 on page 8 of the instant specification following the administration of a capsule formulation having tenatoprazole 20 mg and ranitidine 200 mg. Applicants have not shown this combination of tenatoprazole and ranitidine to be markedly superior to the control of gastric acidity compared to the administration of each component alone. Improvement of symptoms is entirely expected.

A reference may be applied not only for what it expressly teaches by direct anticipation, but also for what one of ordinary skill in the art might reasonably infer from the teachings. See *In re Opprecht*, 12 USPQ 2d, 1235, 1236 (Fed. Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). In light of the foregoing, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Facts & Comparisons is applied in the present rejection specifically to show information on dosing, pharmacokinetics and indications of use.

Further, it is not inventive to discover an optimum or workable range by routine experimentation when general conditions of a claim are disclosed in the prior art. See *In re Aller*, 105 USPQ 233,235 (CCPA 1955) and MPEP 2144.05(II). The currently claimed specific weight ratio ranges are not seen to be inconsistent with ranges that would have been determined by the skilled artisan.

Applicants' arguments are not found persuasive. The rejection of record of claims 1-6 and 9-18 under 35 U.S.C. 103 is maintained.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/532,114
Art Unit: 1614

Page 5

/Phyllis G. Spivack/
Primary Examiner, Art Unit 1614

March 8, 2008



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APPLICATION NUMBER	PATENT NUMBER	GROUP ART UNIT	FILE WRAPPER LOCATION
10/532,114		1614	16M1

Correspondence Address / Fee Address Change

The following fields have been set to Customer Number 23911 on 03/17/2008

- Correspondence Address

The address of record for Customer Number 23911 is:

CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON,DC 20044-4300



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CROWELL & MORING LLP
INTELLECTUAL PROPERTY GROUP
P.O. BOX 14300
WASHINGTON,DC 20044-4300

MATTER#	8130119				PRINTED ON:	9/23/2008	
COUNTRY	US UNITED STATES				TITLE	PRIOR 10/21/2003	
NEW/CON	NEW	SERIAL#	10/532.114		Pharmaceutical composition combining tenatoprazole and a histamine h2-receptor antagonist		MAIL
RELATED		PATENT#					FILE 6/23/2006
TYPE	UTL	STATUS	PUBLISHED				PUBL 10/28/2006
CLIENT	104006	Mitsubishi Pharma Corporation			1	CREF 81364US/07111/JL/sub	ISSUE
AGENT	CS	Cabinet Suseur et L'Heigouaich				AREP	1ST 10/21/2003
							EXP 10/21/2023

ID	O	ACTION	BASE	DUE IN	DUE	EXTNS	FINAL	EXT	RESPONSE	CALL UP	1	2	P
PX	Y	PCT Filing Date	10/21/2003								Y	Y	Y
PR	Y	Prelim Amend Filed	4/21/2005								Y	Y	Y
DS	N	Inf Disclosure Stmt	4/21/2005	3/M	7/21/2005	3/1	10/21/2005	0	4/21/2005	1/M	Y	Y	Y
PD	N	Priority claim due	4/21/2005	4/M	8/21/2005		8/21/2005	0	4/21/2005	1/M	Y	Y	Y
G2	N	Missing Parts (2 Mo)	2/1/2006	2/M	4/7/2006	5/1	9/7/2006	0	4/3/2006	2/M	Y	Y	Y
DE	Y	Declaration Filed	5/23/2006								Y	Y	Y
PO	Y	PTO Communication	7/14/2006								Y	Y	Y
This communication is issued in response to the "Renewed Submission Under 37 CFR 1.42" filed by applicants on 6-23-06 GRANTED.													
AT	Y	Notice Acceptance	7/19/2006								Y	Y	Y
G2	N	Missing Parts (2 Mo)	6/19/2006	2/M	8/19/2006	5/1	1/19/2007	0	6/23/2006	2/M	Y	Y	Y
Taken from the Decision Regarding Submission Under 37 CFR 1.42													
SF	N	SC - Filing Receipt	4/21/2005	17/M	9/21/2005		9/21/2005	0	7/19/2005	15/D	Y	Y	Y
Application was filed 4/21/05 PLEASE DO A STATUS													
RE	N	Response to OA	9/11/2006	3/M	12/11/2006	3/1	3/11/2007	3	3/12/2007	2/M	Y	Y	Y
3 MONTH EOT FILED 03/12/07													
DS	Y	Inf Disclosure Stmt	4/12/2007								Y	Y	Y
2nd ids													
RE	N	Response to OA	6/7/2007	3/M	9/7/2007	3/1	12/7/2007	3	12/7/2007	2/M	Y	Y	Y
3 month eot filed 12-7-07													
S2	N	SC - Office Action	12/7/2007	7/M	7/7/2008	3/1	10/7/2008	3		15/D	Y	Y	Y

INVENTORS Schutts, Francois Charbit, Suzy Fichoux, Herve Homerin, Michel Taccoen, Alain (Deceased) Taccoen, Nathalie (Legal Rep) Inaba, Yoshio	ASSIGNEES Sidem Pharma GA Mitsubishi Pharma Corporation
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PRIOR APPLICATIONS						
REFERENCE#	CNTRY	SERIAL#	FILED	TITLE / DESCRIPTION	TYPE	
	FR	03/13114	10/21/2003		APPL	
	WO	FR2003/003124	10/21/2003		APPL	

USER-DEFINABLE FIELDS				PATENT FIELDS								
TEXT 1				SMALL ENTITY	NO	PUBL #	US 2008-0241136 A1					
CPA				IND CLAIMS		ART UNIT	1814					
BI/CAM	1032013-000119			TOTAL CLAIMS		CONFIRM#	9081					
						EXAMINER	SPIVACK, PHYLLIS G					
P26014US00	ENTERED	3/17/2005	MODIFIED	9/8/2005 12	BY	JAY	ATTORNEYS	EJG	/	MMH	/	EJG